

REMARKS/ARGUMENTS

Claims 1-9 are pending, claim 7 having been withdrawn from consideration. By this Amendment, claims 1-6 are amended and new claims 8 and 9 are presented. Support for the amendments to claims 1-6 and new claims 8 and 9 can be found, for example, in the instant specification at page 4, lines 12 to 24, Examples 1 to 4, and in original claims 1-6. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Objection to the Claims

The Office Action objects to claim 1 as including informalities. By this Amendment, claim 1 is amended to obviate the objection. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1-6 as indefinite under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

The Office Action asserts that claim 1 is rendered indefinite by its recitation of the terms "quick water-dissolving film," "cellulose compatible with said starch," and "cosmetic, aromatic, pharmaceutical and/or food substance." The Office Action asserts that claim 2 is rendered indefinite by its recitation of the term "prebiotic, probiotic and symbiotic food bacteria." While Applicants do not necessarily agree with these assertions, claims 1 and 2 have been amended to replace the allegedly indefinite language. Applicants submit that one of ordinary skill in the art could readily discern the metes and bounds of amended claims 1 and 2. Claims 3-6 are rejected solely for their dependency from claims 1 and 2.

For the foregoing reasons, claims 1-6 are definite. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §102

The Office Action rejects claims 1 and 4 under 35 U.S.C. §102(b) over U.S. Patent No. 6,419,903 to Xu et al. ("Xu"). Applicants respectfully traverse the rejection.

Claim 1 recites "[a]n edible film, comprising: at least one starch of low molecular weight and high amylopectin content, the starch being present in an amount of from 20 to 80 % by weight relative to a total weight of the film; at least one cellulose compound ... the at least one cellulose compound being present in an amount of from 15 to 70 % by weight relative to the total weight of the film; and at least one active substance ... being present in an amount of from 10 to 50 % by weight relative to the total weight of the film; wherein: the at least one starch and the at least one cellulose compound are selected so as to be capable of binding to one another in stable form; and the film is composed so that the film will dissolve within 10 seconds of contact with saliva" (emphasis added). Xu does not disclose or suggest such a film.

The Office Action asserts that Xu discloses a rapidly dissolvable orally consumable film composition including water soluble, low viscosity hydroxyalkylmethyl cellulose, water dispersible starch and a flavoring agent. See Office Action, page 4. However, the films of Xu include pre-gelatinized starches, rather than the starch of low molecular weight and high amylopectin content recited in claim 1. See, e.g., Xu, column 3, lines 21 to 40. Such pre-gelatinized starches necessarily gelatinize in the presence of saliva in the mouth, and thus adhere to the surface of the mouth when inserted therein. As a result, the films of Xu dissolve in saliva in a time of from about 30 to 40 seconds. See Xu, column 2, lines 55 to 58. In the only example in Xu, the dissolution time is 40 seconds. See Xu, Table IV. In contrast,

the formulation of claim 1 permits dissolution times of 10 seconds or less. *See* present specification, Examples 1 to 4.

Moreover, the formulation of Xu, which includes different starches and other components in different amounts than recited in claim 1, permits amounts of active ingredient (i.e., flavoring) of from about 2.0 to 10 % by weight. *See* Xu, column 4, lines 3 to 6; Table I. The film of claim 1, by contrast, includes from 10 to 50 % by weight of an active substance. The ability of the film of claim 1 to retain active substances in such large amounts is shown, for example, in Examples 1 to 4 of the present specification. This ability can be attributed, at least in part, to the particular starches employed in the film of claim 1 and their cooperative effect with the other recited components. A film such as recited in claim 1 that can retain large amounts of an active substance provides obvious advantages. For example, because of the quick dissolution rate and large amount of active substance, such a film can be used in drug delivery for oral administration of pharmaceutical substances that are desirably absorbed orally rather than in the intestinal tract (e.g., anti-inflammatories that can adversely affect the stomach) – the pharmaceutical substance is quickly released by the film in the mouth rather than being retained until entry into the intestinal tract. The films of Xu are do not include the components of the film of claim 1 in the particular recited amounts, and thus do not achieve the remarkable properties of the film of claim 1.

As Xu does not disclose or suggest a film including at least one starch of low molecular weight and high amylopectin content and at least one active substance in an amount of from 10 to 50 % by weight that dissolves within 10 seconds of contact with saliva, Xu does not disclose each and every feature of claim 1.

As explained, claim 1 is not anticipated by Xu. Claim 4 depends from claim 1 and, thus, also is not anticipated by Xu. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejections Under 35 U.S.C. §103

A. Cavaliere Vesely

The Office Action rejects claims 1-3 under 35 U.S.C. §103(a) over U.S. Patent No. 5,716,615 to Cavaliere Vesely et al. ("Cavaliere Vesely"). Applicants respectfully traverse the rejection.

Claim 1 is set forth above. The Office Action asserts that Cavaliere Vesely discloses an active ingredient including one or more bacteria in an amount of from 5 to 85 % by weight. *See* Office Action, page 5. The Office Action further asserts that Cavaliere Vesely's general disclosure of using various excipients including cellulose and starch, would have rendered obvious claim 1. Notwithstanding these assertions, Cavaliere Vesely does not disclose or suggest the film of claim 1.

At the outset, Cavaliere Vesely does not disclose an edible film at all. The Office Action makes the bald assertion that because Cavaliere Vesely discloses forms of administration such as capsules and suppositories, it would be obvious to formulate the disclosed compositions as edible films. There is simply no support for this assertion. The mechanics by which an edible film retains and releases an active ingredient, and the formulations which permit such retention and release, are wholly different from the capsules, suppositories, etc., disclosed in Cavaliere Vesely. One of ordinary skill in the art would have no expectation of successfully making an edible film including the active ingredients of Cavaliere Vesely based on its broad disclosure of using excipients and suggestion that capsules, suppositories, etc., are acceptable forms of administration.

Even if it were possible to produce an edible film based on the disclosure of Cavaliere Vesely, which it is not, Cavaliere Vesely fails to disclose or suggest the particular composition of the film of claim 1 or the desirable properties associated with such composition. Claim 1 requires a particular starch and a particular cellulose compound in

particular amounts, which permits an edible film that dissolves within 10 seconds of contact with saliva. Nothing in Cavaliere Vesely would lead one of ordinary skill in the art to such a composition having such properties.

As Cavaliere Vesely fails to disclose or suggest an edible film including the particular components, in the particular amounts, and having the particular properties of the edible film of claim 1, Cavaliere Vesely cannot render claim 1 obvious.

As explained, claim 1 would not have been rendered obvious by Cavaliere Vesely. Claims 2 and 3 depend from claim 1 and, thus, also would not have been rendered obvious by Cavaliere Vesely. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Cavaliere Vesely, Xu and Sharik

The Office Action rejects claims 1-6 under 35 U.S.C. §103(a) over Cavaliere Vesely in view of Xu and U.S. Patent No. 5,206,026 to Sharik ("Sharik"). Applicants respectfully traverse the rejection.

For the reasons discussed above, Cavaliere Vesely and Xu fail to disclose or suggest the film of claim 1. Sharik is cited for its alleged disclosure of films including film-forming polymers such as hydroxyethyl cellulose. However, as Sharik, like Cavaliere Vesely and Xu, fails to disclose or suggest an edible film including the particular components, in the particular amounts, and having the particular properties of the edible film of claim 1, the combination of references cannot render claim 1 obvious.

As explained, claim 1 would not have been rendered obvious by Cavaliere Vesely, Xu and Sharik. Claims 2-6 depend from claim 1 and, thus, also would not have been rendered obvious by Cavaliere Vesely, Xu and Sharik. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

C. Xu, Hata and Sharik

The Office Action rejects claims 1-6 under 35 U.S.C. §103(a) over Cavaliere Vesely in view of U.S. Patent No. 4,345,032 to Hata ("Hata") and Sharik. Applicants respectfully traverse the rejection.

For the reasons discussed above, Xu and Sharik fail to disclose or suggest the film of claim 1. Hata is cited for its alleged disclosure of lactobacillus strains having the ability to deodorize foul breath. However, as Hata, like Xu and Sharik, fails to disclose or suggest a film including an edible film including the particular components, in the particular amounts, and having the particular properties of the edible film of claim 1, the combination of references cannot render claim 1 obvious.

As explained, claim 1 would not have been rendered obvious by Xu, Hata and Sharik. Claims 2-6 depend from claim 1 and, thus, also would not have been rendered obvious by Xu, Hata and Sharik. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Double Patenting

The Office Action provisionally rejects claims 1-6 under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of U.S. Patent Application No. 10/680,115. Applicants submit that the Terminal Disclaimer filed herewith obviates the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 1-9 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

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Terminal Disclaimer